



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/731,412	12/06/2000	Howard Bernstein	ACU 105 DIV(2)	9414

23579 7590 05/28/2002

PATREA L. PABST
HOLLAND & KNIGHT LLP
SUITE 2000, ONE ATLANTIC CENTER
1201 WEST PEACHTREE STREET, N.E.
ATLANTA, GA 30309-3400

EXAMINER

WEBMAN, EDWARD J

ART UNIT	PAPER NUMBER
----------	--------------

1617

DATE MAILED: 05/28/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/731412

Applicant(s)

BERNSTEIN

Examiner

WEBMAN

Group Art Unit

1617

— The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address —

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

☒ Responsive to communication(s) filed on 2/22/02

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

☒ Claim(s) 20-34 is/are pending in the application.

Of the above claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 20-24, 27-32 is/are rejected.

☒ Claim(s) 25, 26, 33, 34 is/are objected to.

☐ Claim(s) _____ are subject to restriction or election requirement

Application Papers

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119 (a)-(d).

☐ All ☐ Some* ☐ None of the:

☐ Certified copies of the priority documents have been received.

☐ Certified copies of the priority documents have been received in Application No. _____

☐ Copies of the certified copies of the priority documents have been received

in this national stage application from the International Bureau (PCT Rule 17.2(a))

*Certified copies not received: _____

Attachment(s)

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 2

☐ Interview Summary, PTO-413

☐ Notice of Reference(s) Cited, PTO-892

☐ Notice of Informal Patent Application, PTO-152

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Other _____

Office Action Summary

The declaration of Dr. H, Bernstein, paper no. 6, filed 2/22/02. Has been considered and is deemed to overcome the rejections over Hanes et al and Hanke et al. Neither reference, as applicants note, teach pore formers.

However, the declaration does not overcome the rejection over Gombotz et al because contrary to applicants assertion, this reference does teach the now claimed pore formers.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 20-24, 27-32 are rejected under 35 U.S.C. 102(e) as being anticipated by Gombotz et al.

Gombotz et al teach injection or transmucosal delivery of microparticles comprising polylactic acid or a biadhesive polymer (abstract).

Cellulose is disclosed (column 5 line 21) 0.1%-10% active is specified (column 9 lines 18-19). 4:1 lipid to active is disclosed (column 10 line 7). Phospholipids are specified (column 10 line 8). Pore formers are disclosed (column 9 lines 51-55).

Claims 20-24, 27-32 are rejected.

Claims 25, 26, 33, 34 are objected to as dependent on a rejected claim.

No claims allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Edward Webman whose telephone number is (703) 308-4432. The examiner can normally be reached on Monday to Friday 9 Am 5 PM.

Art Unit: 1617

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie can be reached on (703) 308-0570. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3592 for regular communications and (703) 305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Webman/LR
May 8, 2002



EDWARD J. WEBMAN
PRIMARY EXAMINER
GROUP 1500